

## PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

### ARTICLE DETAILS

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| <b>TITLE (PROVISIONAL)</b> | Sonic and ultrasonic oscillating devices for the management of pain and dental fear in children or adolescents that require caries removal: A systematic review. |
| <b>AUTHORS</b>             | Cianetti, Stefano; Abraha, Iosief; Pagano, Stefano; Lupatelli, Eleonora; Lombardo, Guido   |

### VERSION 1 – REVIEW

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| <b>REVIEWER</b>        | Mauro Donati<br>Gothenburg University; Sweden |
| <b>REVIEW RETURNED</b> | 08-Dec-2017                                   |

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| <b>GENERAL COMMENTS</b> | <p>Comments:</p> <p>The purpose of the present investigation was to systematically review the current available literature comparing the use of sonic or ultrasonic devices to rotating drills for the management of pain and dental fear in children or adolescents that require caries removal.</p> <p>Although the study has merits to be published some aspects needs to be elucidated.</p> <p>Specific comments are as follows:</p> <p>1) This reviewer has a concern in relation to the scientific question and the relative aim the Authors formulated. Generally the aim of Systematic Review is to review the current available literature based on a relevant scientific question. The aim reported by the Authors is more appropriate for a RCT or CCT not for a SR. I therefore suggest to rephrase the aim of the study and then to address separately the main scientific question of the review (e.g. “Are sonic and ultrasonic devices effective in the management of pain and dental fear in children or adolescents that require caries removal?”). Please observe that the main conclusion of the review has to be in line with the information and meta-analysis (if carried out) retrieved and conducted in the review. If the review has not enough information (according to the criteria selected) to answer to the scientific main question, the main</p> |
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|  | <p>conclusion has to refer to the lack of available literature to answer at the question. The conclusion the Authors reported is more appropriate to a RCT or CCT trial with that particular aim. Conventionally the aim of a SR is to evaluate in a meta-analysis, results from different studies that are underpowered to provide a single “stronger” estimate of the treatment effect.</p> <p>2) Systematic Reviews with 2 or more Reviewers usually report measure of agreement in study selection and quality appraisal (K statistic). Did the Authors consider this issue?</p> <p>3) In Table 1 the reference Li et al. 2006 does not have correspondence on the reference list. However in the reference list it is present the publication of Li et al 2010. This reviewer has concern on the agreement about the reference reported in the table and in the list.</p> <p>4) In the table 1 the reference Li et al. reported a number subject recruited of 93, while in the study by Li et al. 2010 the number of patients recruited is 72. I would therefore suggest to double check the information reported in the table</p> <p>1.</p> <p>5) The two studies included are both split-mouth designed. It is assumed that both treatments are carried out in the same patient. Have the Authors considered as a possible bias of the studies a “carryover effect” of one of the treatment influencing pain perception to the second treatment? If the Authors deem relevant this item, a pertinent comment would be appropriate on the discussion section.</p> <p>6) Page 5 line 7, I would rather write “...the need of RCTs instead of need of SR</p> <p>7) Few misprints deserve some attention (e.g. page 6 line 23 “fillings”; page 4 line 45 check sentence; page 12 line 10 check sentence). I suggest therefore a further “check-up” of the entire document.</p> |
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| <b>REVIEWER</b>        | Laura D. Seligman<br>University of Texas Rio Grande Valley<br>United States |
| <b>REVIEW RETURNED</b> | 25-Dec-2017   |

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| <b>GENERAL COMMENTS</b> | <ul style="list-style-type: none"> <li>This biggest issue is that it is not clear to me the authors were able to achieve the goal of the paper. More specifically, they were only able to identify two studies that met the inclusion criteria. Both studies were judged to be of low quality (high risk of bias). One study included only dentist ratings of cooperation with no self-report of fear – cooperation and fear/anxiety are not necessarily the same thing. The second study explicitly excluded children with dental anxiety or uncooperative behavior – the population which one could</li> </ul> |
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|                         | <p>argue would likely be most of interest. This study had no outcomes related to anxiety. Given the limited number of studies and the limitations in the studies, it is not clear to me that a systematic review provides any meaningful information to address whether sonic and ultrasonic oscillating devices are effective for the management of pain and dental fear in youth.</p> <p>Minor points:</p> <ul style="list-style-type: none"> <li>• Errors in a couple of places make it difficult to understand parts of the introduction – this is particularly an issue in the 2nd to last paragraph in which the authors present the argument supporting the need for this study.</li> <li>• Figure 1 - reason for excluding studies should be given here rather than in an appendix.</li> <li>• When effects of intervention are reported the results for discomfort in the Li study are hard to interpret because the level of discomfort for the control condition is not given.</li> </ul> |
| <b>REVIEWER</b>         | <p>Changyong Feng<br/>Department of Biostatistics<br/>University of Rochester Medical Center<br/>601 Elmwood Ave., Box 630<br/>Rochester, NY 14642<br/>USA</p>   |
| <b>REVIEW RETURNED</b>  | 23-Jan-2018  |
| <b>GENERAL COMMENTS</b> | <p>This a very low level paper. Although it is called a systematic review, the manuscript reviewed only two published papers. The did some naive analyses based on the summary data within each paper. The statistical method is totally. The Wilcoxon signed rank test cannot be used to compare two proportions.</p>   |

### VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

Reviewer Name

Mauro Donati

Institution and Country Gothenburg University; Sweden

Please leave your comments for the authors below

The purpose of the present investigation was to systematically review the current available literature comparing the use of sonic or ultrasonic devices to rotating drills for the management of pain and dental fear in children or adolescents that require caries removal. Although the study has merits to be published some aspects needs to be elucidated.

\*\*We thank very much dr. Donati for spending his time in revising our manuscript. This review study has been revised almost entirely with particular emphasis in the Results especially after obtaining the translation of one of the two trials, the Discussion and the rationale within the Introduction. In addition, we amended the Methods section especially regarding the statistical analysis

Reviewer: 2

Reviewer Name

Laura D. Seligman

Institution and Country

University of Texas Rio Grande Valley United States

Please leave your comments for the authors below

- This biggest issue is that it is not clear to me the authors were able to achieve the goal of the paper. More specifically, they were only able to identify two studies that met the inclusion criteria. Both studies were judged to be of low quality (high risk of bias). One study included only dentist ratings of

cooperation with no self-report of fear – cooperation and fear/anxiety are not necessarily the same thing.

\*\* We thank very much Dr. Seligman for spending her time in revising our manuscript. Indeed, we found that there was a mistake in the name of the scale which we have now modified. In addition, while in principle we agree that cooperation and fear/anxiety are not necessarily the same thing, we have to clarify that the Venham Rating Scale is an exceptional scale in that it measures both cooperation and anxiety. However, Li et al provided a modified version of the scale in which both elements are expressed in a single value. The modified version of the Venham scale was not validated and we did discuss this point in the paper as follows: “In addition, in one trial Li and co-authors rated both the cooperation level and anxiety shown by children in the dental chair by using a modified version of a rating scale named Venham Rating Scales for Anxiety and Uncooperative Behavior. Usually, all rating scales (based on a dentist assessment) are considered a valid tool to perform a child’s behaviour cooperation assessment rather than an anxiety evaluation<sup>53</sup>. The above-mentioned Venham Rating Scale represents an exception to this rule. This scale, indeed, is composed of two subscales: an Anxiety Rating Scale to measure dental fear and a Behavior Rating Scale to evaluate the child’s cooperation. The reliability and validity of this scale has been directly demonstrated by Venham some years after its realization <sup>54</sup>. However, in the Li and co-authors’ study, as well-outlined before, a modified version of Venham Rating Scales for Anxiety and Uncooperative Behavior (composed of only one scale) was used and no validation studies about that were found. Consequently, unresolved concerns remain about the validity of anxiety and cooperation values measured in the Li and co-authors’ study.”.

- The second study explicitly excluded children with dental anxiety or uncooperative behavior – the population which one could argue would likely be most of interest. This study had no outcomes related to anxiety.

\*\*We agree with Dr. Seligman that “ Chomyszyn-Gajewska and co-authors excluded from their study sample dental anxious and/or uncooperative children, whereas those represent the target population of greatest interest for the present review. This particular group of patients indeed is the one that should be most advantaged by anxiety management procedures . Therefore, data derived from only non-anxious and dental care compliant patients (for whom ordinarily no anxiety management is required) generate doubts on their value in terms of applicability (indirectness)<sup>54</sup> and relevance to improve the clinical practice. We have discussed this as follows: “This particular group of patients, indeed, is the one most advantaged by anxiety management procedures. Therefore, data derived from only non-anxious and dental care compliant patients (for whom ordinarily no anxiety management is required) generate doubts on their value in terms of applicability (indirectness)<sup>55</sup> and relevance to improve the clinical practice. However, when children are considered during treatment of dental caries, they should be always deemed as at risk of developing dental fear particularly when they are younger<sup>9 56</sup>. Unpleasant experiences, particularly when pain was felt during the earliest dental visits, represent an extremely relevant risk factor for children to develop dental anxiety<sup>25 57-59</sup> that should be carefully avoided with an adequate dentist-child relationship.”

-Given the limited number of studies and the limitations in the studies, it is not clear to me that a systematic review provides any meaningful information to address whether sonic and ultrasonic oscillating devices are effective for the management of pain and dental fear in youth.

\*\*As reported in the manuscript, the present work has been done within a large project regarding the evaluation of treatment, prevention of anxiety especially using a non-pharmacological intervention as is the ultrasonic device. In addition, the present work has been anticipated by a published protocol. It is important for us to have conducted a review based on a transparently and systematic approach to gather the evidence.

Minor points:

- Errors in a couple of places make in it difficult to understand parts of the introduction – this is particularly an issue in the 2nd to last paragraph in which the authors present the argument supporting the need for this study.

\*\*We have reformulated the second part of the Introduction paragraph trying to better explain the clinical utility of this review as follows: “Despite the proven effectiveness of traditional low and high speed rotating instruments to remove caries and to prepare cavities for dental fillings, these instruments could be inappropriate when a certain strata of the population with evident dental anxiety (12.2-20%), such as young children, are treated by dentists 9. In many cases, the use of traditional rotating burs to remove caries is combined with local administration of anaesthesia. Anaesthetic injection notoriously represents one of the most significant dental anxiety triggers, reducing compliance with dental treatment 10 11 12 13 14 15 16. Furthermore, sight of the traditional rotating drill, as well as the vibration and noise felt by patients during treatment, represents another important dental anxiety stimulus that could be avoided by new approaches and alternative devices used in the management of caries 10 17 11 18 14.

Sonic and ultrasonic devices belong to an alternative group of so-called “micro-traumatic” tools to remove caries that include several other alternative devices/approaches to rotating instruments. The most noteworthy are Atraumatic Restorative Techniques (ART) 19 , chemo chemical removal of caries 20, lasers 21, air abrasion and polymer rotary burs 22. Oscillating devices, therefore, are potentially useful tools to treat caries with a “psychological micro-invasive approach” reducing the recourse to more complicated pharmacological procedures, such as conscious sedation or general anaesthesia. It is well reported that psychological condition impacts the childrens’ and adolescents’ oral health status 10 13 23 24, by conditioning their dental service attendance as well as their compliance with treatment 17 25-29. Hence, sonic and ultrasonic ablation devices can be attractive alternative tools with which to overcome concerns regarding dental anxiety.

The aim of the present investigation was to systematically review the current available literature comparing the use of sonic or ultrasonic devices to rotating drills for the management of pain and dental fear in children or adolescents who require caries removal”.

- Figure 1 - reason for excluding studies should be given here rather than in an appendix.

\*\* we have now provided number and reason for exclusion in the Appendix.

- When effects of intervention are reported the results for discomfort in the Li study are hard to interpret because the level of discomfort for the control condition is not given.

\*\*We thank very much Dr. Seligman for raising this point. We were now able to translate the paper by Li 2010 and revised the results regarding the outcome discomfort and the other outcomes.

Reviewer: 3

Reviewer Name

Changyong Feng

Institution and Country

Department of Biostatistics

University of Rochester Medical Center

601 Elmwood Ave., Box 630

Rochester, NY 14642

USA

Please state any competing interests or state ‘None declared’:

None declared

Please leave your comments for the authors below

This a very low level paper. Although it is called a systematic review, the manuscript reviewed only two published papers. The did some naive analyses based on the summary data within each paper.

The statistical method is totally. The Wilcoxon signed rank test cannot be used to compare two proportions.

\*\* We thank Dr. Feng for his comment. We think that our review has been performed with a transparent and systematic approach. We agree that it had several weakness that at this stage has been addressed and helped improving the manuscript. Our systematic approach identified only two studies that were of low quality. We revised the statistics methods and were able to provide risk ratios using the method described by Elbourne 2002 that is useful to address issues regarding parallel or cross-over design. However, the data within these trials were limited that hindered us to perform meta-analysis. However, we completely revised the results of our manuscript after carefully reviewing again the included studies

#### FORMATTING AMENDMENTS (if any)

Required amendments will be listed here; please include these changes in your revision

#### Reviewer comments

Manuscript ID: bmjopen-2017-020840

Title: Sonic and ultrasonic oscillating devices for the management of pain and dental fear in children or adolescents that require caries removal. A systematic review.

#### Comments:

The purpose of the present investigation was to systematically review the current available literature comparing the use of sonic or ultrasonic devices to rotating drills for the management of pain and dental fear in children or adolescents that require caries removal.

Although the study has merits to be published some aspects needs to be elucidated. Specific comments are as follows:

1) This reviewer has a concern in relation to the scientific question and the relative aim the Authors formulated. Generally the aim of Systematic Review is to review the current available literature based on a relevant scientific question. The aim reported by the Authors is more appropriate for a RCT or CCT not for a SR. I therefore suggest to rephrase the aim of the study and then to address separately the main scientific question of the review (e.g. " Are sonic and ultrasonic devices effective in the management of pain and dental fear in children or adolescents that require caries removal?"). Please observe that the main conclusion of the review has to be in line with the information and meta-analysis (if carried out) retrieved and conducted in the review. If the review has not enough information (according to the criteria selected) to answer to the scientific main question, the main conclusion has to refer to the lack of available literature to answer at the question. The conclusion the Authors reported is more appropriate to a RCT or CCT trial with that particular aim. Conventionally the aim of a SR is to evaluate in a meta-analysis, results from different studies that are underpowered to provide a single "stronger" estimate of the treatment effect.

\*\* We thank the Editor for this comment. We have now introduced the review's question after the introduction and revised the conclusions accordingly.

2) Systematic Reviews with 2 or more Reviewers usually report measure of agreement in study selection and quality appraisal (K statistic). Did the Authors consider this issue?

\*\* Data were abstracted independently. The  $\kappa$  statistic was almost perfect. ( $\kappa > 0.94$ ) and that has been added in the review main text.

3) In Table 1 the reference Li et al. 2006 does not have correspondence on the reference list. However in the reference list it is present the publication of Li et al 2010. This reviewer has concern on the agreement about the reference reported in the table and in the list.

\*\* We have amended the year

4) In the table 1 the reference Li et al. reported a number subject recruited of 93, while in the study by Li et al. 2010 the number of patients recruited is 72. I

would therefore suggest to double check the information reported in the table 1.

\*\* we have amended as 72 were the participants while 93 were the decayed teeth in each group.

5) The two studies included are both split-mouth designed. It is assumed that both treatments are carried out in the same patient. Have the Authors considered as a possible bias of the studies a “carryover effect” of one of the treatment influencing pain perception to the second treatment? If the Authors deem relevant this item, a pertinent comment would be appropriate on the discussion section.

\*\* we thank the Editor for this comment. We have now considered this issue and included a comment as follows: “Moreover, a further consideration is required about the design of the two included studies in this review. Both trials presented a split mouth design that might be considered a particular type of crossover study. In both study designs the same patient is treated at two different times (one decayed tooth on each side of the mouth, one at a time) with alternating intervention and control devices for caries removal. The crossover study presents two relevant advantages over the most commonly adopted parallel study design : (1) the need of a lower sample size to obtain the same level of precision and statistical power, (2) a more accurate comparison between two different interventions due to the fact that single patient variations are lower than between different -patients. However crossover design could present a risk of a “carryover effect” biasing the results . This effect is that the emotional impact of the patient’s first dental visit lingering in his or her memory, might affect perception of a second intervention and influence his or her pain perception 62

6) Page 5 line 7, I would rather write “...the need of RCTs instead of need of SR

\*\* we thank the Editor for this comment. The sentence was removed for other requirements.

7) Few misprints deserve some attention (e.g. page 6 line 23 “fillings”; page 4 line 45 check sentence; page 12 line 10 check sentence). I suggest therefore a further “check-up” of the entire document.

\*\* we thank the Editor for this comment. We modified or eliminated the sentences as necessary.